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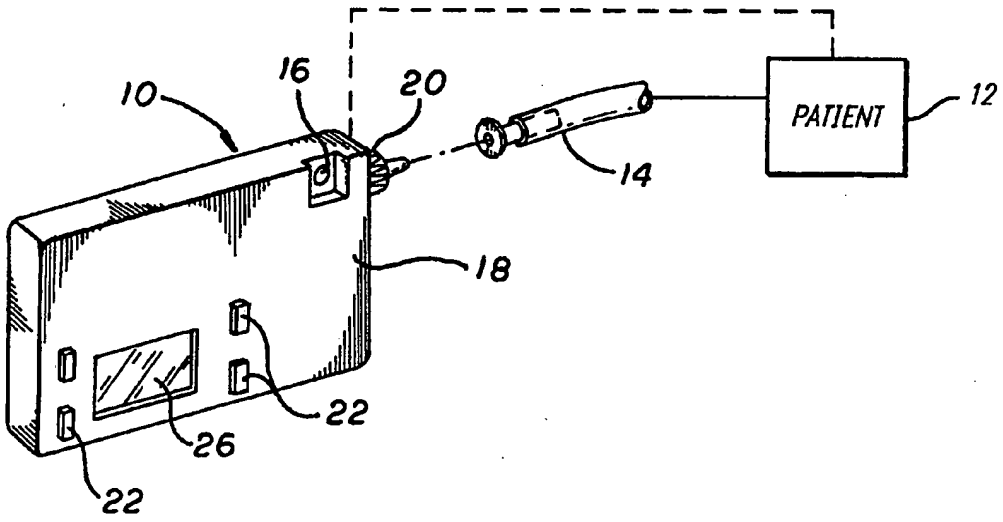

(57) Abstract

A medication infusion device (10) such as a programmable infusion pump includes data input regarding a selected patient parameter such as a current blood glucose reading. The infusion device includes a controller responsive to this data input to develop a medication delivery protocol.

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MEDICATION INFUSION DEVICE WITH BLOOD GLUCOSE DATA INPUT

BACKGROUND OF THE INVENTION

This invention relates generally to improvements in medication infusion devices for use in delivering a selected medication to a patient. More specifically, this invention relates to a medication infusion device such as a programmable infusion pump or similar apparatus adapted for response to a parameter indicative of patient condition, such as a current blood glucose reading.

Infusion pump devices and systems are generally known in the medical arts, for use in delivering or dispensing a prescribed medication to a patient. In one form, such devices comprise a relatively compact pump housing adapted to receive a syringe carrying a prescribed medication such as insulin for administration to a patient through infusion tubing and an associated catheter or the like. The infusion pump operates a small drive motor connected to a syringe piston plunger to administer the medication to the patient.

Programmable control means are normally provided for operating the pump drive motor continuously, or at periodic intervals, to obtain a

closely controlled and accurate delivery of medication over an extended time period. Such infusion pumps are utilized to administer insulin and other medications, with an exemplary pump construction being shown and described in U.S. Patents 4,562,751; 4,678,408; and 4,685,903.

A typical programmable infusion pump includes a plurality of externally accessible control switches or buttons which can be manipulated in relation to a visual display to program the pump in accordance with patient medication requirements. Initial pump programming is normally performed by the patient's physician or by other medical personnel. However, particularly in the case of infusion pumps used to administer insulin to diabetic patients, the control buttons and related pump control circuitry are often designed to accommodate at least some patient intervention to vary medication delivery times and doses in accordance with anticipated patient requirements.

One alternative medication infusion device comprises a compact syringe-type implement constructed to resemble a fountain pen or the like, and thus adapted to be carried easily and conveniently by the patient. See, for example, U.S. Patents 5,383,865 and 5,391,157, and European Patent Publication 0,554,995. Such pen-like implements include a rotatable dial or knob for retracting a syringe plunger through a predetermined stroke, with a visual display providing an indication of the medication units or volume to be delivered upon subsequent manual advancement of the plunger. The patient can thus set the implement to deliver a desired dosage, and then press the plunger to deliver the medication. The medication dosage and frequency are, of course, developed according to a dispensing protocol to meet the needs of each specific patient.

In recent years, there has been considerable interest in the development of improved medication infusion devices which can be used to deliver medication to the patient in accordance with current or actual patient requirements, as distinguished from anticipated medication requirements. In this regard, blood chemistry readings can provide current information regarding important patient condition parameters that can affect current or actual patient medication requirements. For example, blood glucose readings represent key data that can be used to determine current insulin requirements of a diabetic patient. Extensive research is ongoing with respect to the development of improved and reliable glucose sensors, for example, as described in U.S. Patents 4,650,547; 4,671,288; 4,781,798; 4,703,756; and 4,890,620. Similarly, a variety of systems have been proposed for use of a glucose sensor to automatically alter the operation of a medication infusion pump in response to current patient requirements, as described, for example, in U.S. Patents 4,633,878; 3,837,339; 5,101,814; and 5,372,133.

While automatic control of an infusion device for insulin or other medication appears to be a desirable approach for some patients, diabetic patients often need more flexibility in their individual medication delivery protocols in order to accommodate a normal daily living schedule. That is, while a current blood glucose reading is an important factor in determining medication requirements, variable daily activity such as changing eating schedules, exercising schedules, etc., should be taken into account in determining the actual dosage and timing of medication delivery to each individual patient.

There exists, therefore, a significant need for further improvements in medication infusion devices of the type adapted for response to a current patient condition parameter, such as a current blood glucose reading, wherein actual dispensing of medication to the patient represents a balanced response which considers the monitored parameter in addition to current subjective patient activity factors. The present invention fulfills these needs and provides further related advantages.

SUMMARY OF THE INVENTION

In accordance with the invention, an improved medication infusion device includes data input pertaining to a current patient condition parameter, such as a current blood glucose reading, and responds thereto to provide an appropriate medication delivery protocol for the patient. This medication delivery protocol can be implemented automatically, recommended via a visual display for convenient acceptance or rejection by the patient, or otherwise overridden in favor of a different or modified medication delivery protocol. Thus, depending upon subjective factors such as current patient activity, eating schedules, etc., the parameter-responsive protocol can be accepted or modified to best suit the individual patient.

In one preferred form, the medication infusion device comprises a compact programmable medication infusion pump adapted to receive and support a syringe carrying a prescribed medication such as insulin. The infusion pump has manual control switches or buttons which can be operated in association with a visual display to program a pump controller for delivering the medication to the patient in accordance with a predetermined dispensing

protocol. The pump further includes a sensor or meter for detecting or receiving a current patient parameter, such as a blood glucose reading. The parameter sensor or meter provides a data input to the pump controller for altering the medication delivery protocol in an appropriate manner. In accordance with the invention, the altered protocol can be automatically implemented, but may in the alternative be recommended to the patient by means of the visual display for convenient acceptance or rejection by manipulation of one or more of the control buttons, or otherwise overridden entirely by the patient in favor of a different or modified delivery protocol.

In an alternative form of the invention, the medication infusion device comprises a manually operated syringe-type implement, such as a medication delivery pen of the general type described in European Patent Publication 0,554,995. The delivery pen includes a manually adjustable dial or the like for retracting a syringe plunger through a predetermined stroke, in association with a visual display which indicates the medication dosage to be delivered upon subsequent plunger advancement. The delivery pen includes a controller which receives a patient parameter input from a sensor or meter, such as a current blood glucose reading. The controller responds to the data input representing the patient parameter to recommend a dispensing protocol which can be accepted or modified by the patient.

In a further alternative form of the invention, the sensor or meter may be provided for substantially continuous in vivo patient monitoring, such as an implanted or subcutaneous glucose sensor. The in vivo sensor is associated with a radio telemetry transmitter for sending a patient parameter signal to the infusion device which includes a

receiver. The controller of the infusion device responds to the telemetered data input to recommend a medication delivery protocol which can be followed or modified by the patient.

Other features and advantages of the present invention will become more apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate the invention. In such drawings:

FIGURE 1 is an exploded perspective view, shown somewhat in schematic form, illustrating a medication infusion pump with patient parameter data input, in accordance with the novel features of the invention;

FIGURE 2 is a block diagram illustrating operation of the infusion pump of FIG. 1;

FIGURE 3 is a flow chart illustrating operation of the pump controller and recommended dispensing protocol in response to a current patient parameter;

FIGURE 4 is an exploded perspective view, shown somewhat in schematic form, depicting one alternative preferred form of the invention; and

FIGURE 5 illustrates, somewhat in schematic form, a further modified arrangement of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the exemplary drawings, a medication infusion device such as a programmable infusion pump is referred to generally in FIGURE 1 by

the reference numeral 10. The pump 10 is designed for programmable delivery of a selected medication such as insulin to a patient 12 via a length of infusion tubing 14 and a suitable catheter (not shown). The illustrative pump 10 includes a glucose sensor or meter 16 for receiving and/or deriving an indication of current blood glucose level so that a medication delivery protocol can be modified, as desired.

The infusion pump 10 shown in FIG. 1 has an overall construction and operation which is generally known in the art. More specifically, the infusion pump 10 comprises a relatively compact pump case or housing 18 adapted to receive and support a syringe (not shown) charged with a selected medication, such as insulin, to be administered to a patient. The medication-containing syringe carries a luer fitting 20 which protrudes outwardly from one side of the pump housing 18 for suitable connection to the infusion tubing 14 through which the medication is delivered to the patient 12. The pump includes an externally exposed array of actuator key switches or buttons 22 for use in operating and/or programming an internal pump controller 24 (FIG. 2). A visual display 26 is provided on the face of the pump housing 18 for displaying information regarding pump programming and/or pump operation. Infusion pumps of this general type are depicted in U.S. Patents Nos. 4,562,751; 4,678,408; and 4,685,903; which are incorporated by reference herein.

In accordance with one aspect of the invention, the pump controller 24 responds to a data input from the glucose sensor or meter 16, in addition to manually inputted instructions by means of the buttons 22. The glucose sensor or meter 16 is conveniently mounted directly onto the pump housing 18 in a readily accessible position, depending upon

the type of glucose sensor or meter used. In one form, a sensor adapted for receiving and reading a glucose test strip can be incorporated into the pump 10, such as a built-in sensor of the type generally available from Miles Inc., of Elkhart, Indiana, under the name Glucometer. Alternately, the sensor or meter 16 may be coupled in a suitable manner to an implantable or subcutaneous glucose sensor of the type described, for example, in U.S. Patents 4,650,547; 4,671,288; 4,781,798; 4,703,745; and 4,890,620. In either case, data input is provided to the controller 24, as depicted in FIG. 2, so that pump operation may be regulated in accordance with controller programming and in response to a current patient condition parameter such as blood glucose level.

With reference to FIGS. 2 and 3, the controller 24 responds to manipulation of the buttons 22 in addition to the glucose reading data input to operate a pump element 28 which delivers the medication to the patient 12 from a storage reservoir 30, such as a syringe carried by the housing 18. Pursuant to one primary aspect of the present invention, the controller 24 functions in combination with the display 26 and the buttons 22 to provide the patient with important alternatives before actual medication delivery.

More specifically, as shown in the flow chart of FIG. 3, the controller 24 responds to the initial programming and the glucose reading to provide the patient with one of three different protocol alternatives. In one mode of operation, the controller 24 can be set to operate the pump element 28 automatically, by implementing any dispensing protocol modification which is recommended by the controller software, in response to the glucose reading data input. Such automatic implementation of

a modified dispensing protocol is depicted by block 32 in FIG. 3.

As one import alternative, the controller software can be set to provide a recommended dispensing protocol which can be visually displayed to the patient by means of the display 26. This recommended protocol step is illustrated in FIG. 3 by block 34. In this flow path, the patient 12 has an opportunity to accept or reject the recommended modified protocol by appropriate manipulation of the buttons 22, as represented by block 36 in FIG. 3. Upon acceptance of the recommended modified protocol, the controller 24 operates the pump the deliver medication in accordance therewith. Upon rejection of the recommended protocol, the controller 24 will deliver medication in accordance with a preset or default protocol previously programmed into the controller 24.

As a further alternative, the controller software can regulate controller operation to permit patient implementation of a modified manually inputted protocol, as indicated by block 38 in FIG. 3. Such implementation of a modified manually inputted protocol would normally occur after rejection of the proposed modified protocol, per block 36, so that the precise dosage and/or timing thereof can be varied according to actual patient activity, eating schedules, etc.

Accordingly, the present invention provides the patient with a high degree of flexibility in adapting and/or modifying a medication dispensing protocol as a function of current glucose blood level readings. The dispensing protocol can be adjusted to reflect current patient activity and other subjective considerations, whereby the actual dosage and timing of such dosages can be uniquely tailored to suit the needs of an individual patient.

FIGURE 4 shows an alternative form of a medication infusion device which can be operated in accordance with the present invention. As shown, the infusion device comprises a medication delivery pen 10′ of the general type disclosed in European Patent Publication 0,554,995, which is incorporated by reference herein. The pen comprises a barrel 40 of generally cylindrical shape for receiving a cartridge (not shown) charged with a selected medication such as insulin for a diabetic. A dial or knob 42 on the aft end of the pen is rotatable to mechanically retract a plunger 44 a preselected distance so that a dial-in medication dosage can be administered to a patient upon subsequent manual plunger depression. A display 26′ on the pen barrel 40 displays the dosage to be administered (typically in units), as the dial 42 is rotated. A glucose sensor or meter 16′ of the type previously described, such as a built-in sensor for receiving and reading a glucose test strip, provides a data input to the delivery pen 10′. An internal controller (not shown in FIG. 4) responds to the data input to provide a recommended medication dispensing protocol via the display 26′. As previously discussed, the patient may operate the dial 42 and plunger 44 to deliver the recommended dosage, or a modified dosage in accordance with current patient activity and requirements. The internal controller may store a record of actual dispensing events, for subsequent downloading and/or visual display.

FIGURE 5 shows another alternative form of the invention, wherein an in vivo glucose sensor 16″ is shown implanted within the body of a patient to provide continuous glucose level readings or readings which may otherwise be taken whenever needed. Alternately, a subcutaneous sensor may be used.

An implanted sensor may be constructed in accordance with copending U.S. Serial No. 231,800, whereas a subcutaneous sensor and related sensor inseration set may be constructed generally in accordance with U.S. Patent 5,390,671, both of which are incorporated by reference herein. The sensor 16'' is associated with a transmitter 46 used to send an appropriate glucose data signal via radio telemetry or infrared transmission to an appropriate receiver provided as part of the medication infusion device 10'', which may be constructed generally in accordance with the pump 10 shown in FIG. 1. In this system arrangement, the radio telemetered glucose data signal is inputted to the pump 10'', which then operates a pump controller (not shown) in accordance with the protocol flow paths described previously with respect to FIG. 3.

A variety of further modifications and improvements to the medication infusion device of the present invention will be apparent to those skilled in the art. Accordingly, no limitation on the invention is intended by way of the foregoing description and accompanying drawings, except as set forth in the appended claims.

WHAT IS CLAIMED IS:

1. A medication infusion device, comprising:

reservoir means for receiving and storing a supply of a selected medication;

delivery means for delivering a selected dosage of the medication from said reservoir means to a patient;

controller means for recommending a medication dispensing protocol; and

means for inputting data to said controller means, said data being representative of a current patient condition parameter, said controller means being responsive to said data for recommending said medication dispensing protocol.

2. The medication infusion device of claim 1 further including display means for displaying information pertaining to said medication dispensing protocol.

3. The medication infusion device of claim 1 wherein the patient condition parameter comprises a current blood glucose reading.

4. The medication infusion device of claim 3 wherein said device includes a housing having said reservoir means and said delivery means and said controller means mounted therein, said means for inputting data comprising a blood glucose sensor mounted on said housing.

5. The medication infusion device of claim 3 wherein said device includes a housing having said reservoir means and said delivery means and said controller means mounted therein, said means for inputting data comprising an in vivo sensor mounted on the patient and communicatively coupled to said controller means.

6. The medication infusion device of claim 5 wherein said in vivo sensor comprises an implanted sensor.

7. The medication infusion device of claim 5 wherein said in vivo sensor comprises a subcutaneous sensor.

8. The medication infusion device of claim 5 wherein said in vivo sensor is coupled to said controller means by telemetry.

9. The medication infusion device of claim 1 wherein said controller means automatically operates said delivery means to deliver the selected medication dosage to the patient, said controller means being programmable for operating said delivery means according to a first medication dispensing protocol, said controller means being responsive to said data to recommend a second medication dispensing protocol, said controller means including patient accessible manual set means for enabling said controller means to deliver the medication to the patient according to a selected one of said first and second medication dispensing protocols.

10. The medication infusion device of claim 9 wherein said manual set means is further operable for enabling said controller means to deliver the

medication according to a third manually inputted medication dispensing protocol.

11. A medication infusion device, comprising:

a housing having reservoir means for receiving and storing a supply of a selected medication;

delivery means on said housing for delivering a selected dosage of the medication from said reservoir means to a patient;

controller means for recommending one of a plurality of different medication dispensing protocols;

means for inputting data to said controller means, said data being representative of a current patient condition parameter, said controller means responding to said data to select the medication dispensing protocol to be recommended; and

display means on said housing for displaying the recommended medication dispensing protocol.

12. The medication infusion device of claim 11 wherein said delivery means is automatically operated by said controller means to deliver the selected medication dosage to the patient, said controller means being programmable for operating said delivery means according to a first medication dispensing protocol, said controller means being responsive to said data to recommend a second medication dispensing protocol, said controller means including patient accessible manual set means for enabling said controller means to deliver the medication to the patient according to a selected one of said first and second medication dispensing protocols.

13. The medication infusion device of claim 12 wherein said manual set means is further operable for enabling said controller means to deliver the medication according to a third manually inputted medication dispensing protocol.

14. The medication infusion device of claim 11 wherein said delivery means is manually operated by the patient.

15. The medication infusion device of claim 11 further including display means for displaying information pertaining to said medication dispensing protocol.

16. The medication infusion device of claim 15 wherein said means for inputting data comprising a blood glucose sensor mounted on said housing.

17. The medication infusion device of claim 15 wherein said means for inputting data comprises an in vivo sensor mounted on the patient and communicatively coupled to said controller means.

18. The medication infusion device of claim 17 wherein said in vivo sensor comprises an implanted sensor.

19. The medication infusion device of claim 17 wherein said in vivo sensor comprises a subcutaneous sensor.

20. The medication infusion device of claim 17 wherein said in vivo sensor is coupled to said controller means by telemetry.

21. In a medication infusion device having a reservoir for receiving and storing a supply of a selected medication, and delivery means for delivering a selected dosage of the medication from the reservoir to a patient, a method of operating said infusion device comprising the steps of:

inputting data representative of a current patient condition parameter to a controller having a plurality of different medication dispensing protocols programmed therein;

responding to the inputted data to recommend a selected medication dispensing protocol from the plurality programmed into the controller; and

operating the delivery means to deliver medication to the patient according to one of the recommended medication dispensing protocol or a different dispensing protocol.

22. The method of claim 21 further including displaying the recommended dispensing protocol.

23. The method of claim 21 wherein the patient condition parameter comprises a current blood glucose reading.

AMENDED CLAIMS
[received by the International Bureau on 10 September 1996 (10.09.96); original claims 1-23 replaced by amended claims 1-14 (3 pages)]

1. A medication infusion device, comprising:

reservoir means for receiving and storing a supply of a selected medication;

delivery means for delivering a selected dosage of the medication from aid reservoir means to a patient;

controller means for recommending operation of said delivery means to deliver the selected medication to the patient according to a first medication dispensing protocol; and

means for inputting data to said controller means, said data being representative of a current patient condition parameter, said controller means being responsive to said data for recommending a second medication dispensing protocol;

said controller means including patient accessible manual set means for enabling said controller means to deliver the medication according to a selected one of said first and second medication dispensing protocols.

2. The medication infusion device of claim 1 further including display means for displaying information pertaining to said medication dispensing protocol.

3. The medication infusion device of claim 1 wherein the patient condition parameter comprises a current blood glucose reading.

4. The medication infusion device of claim 3 wherein said device includes a housing having said reservoir means and said delivery means and said controller means mounted therein, said means for inputting data comprising a blood glucose sensor

mounted on said housing.

5. The medication infusion device of claim 3 wherein said device includes a housing having said reservoir means and said delivery means and said controller means mounted therein, said means for inputting data comprising an in vivo sensor mounted on the patient and communicatively coupled to said controller means.

6. The medication infusion device of claim 5 wherein said in vivo sensor comprises an implanted sensor.

7. The medication infusion device of claim 5 wherein said in vivo sensor comprises a subcutaneous sensor.

8. The medication infusion device of claim 5 wherein said in vivo sensor is coupled to said controller means by telemetry.

9. The medication infusion device of claim 1 wherein said controller means automatically operates said delivery means to deliver the selected medication dosage to the patient according to said first medication dispensing protocol, said manual set means enabling said controller means to deliver the medication to the patient according to a selected one of said first and second medication dispensing protocols.

10. The medication infusion device of claim 1 wherein said manual set means is further operable for enabling said controller means to deliver the medication according to a third manually inputted medication dispensing protocol.

11. The medication infusion device of claim 1 wherein said delivery means is manually operated by the patient.

12. In a medication infusion device having a reservoir for receiving and storing a supply of a selected medication, and delivery means for delivering a selected dosage of the medication from the reservoir to a patient, a method of operating said infusion device comprising the steps of:

inputting data representative of a current patient condition parameter to a controller having a plurality of different medication dispensing protocols programmed therein;

responding to the inputted data to recommend a selected medication dispensing protocol from the plurality programmed into the controller; and

operating the delivery means to deliver medication to the patient according to one of the recommended medication dispensing protocol or a different dispensing protocol.

13. The method of claim 12 further including displaying the recommended dispensing protocol.

14. The method of claim 12 wherein the patient condition parameter comprises a current blood glucose reading.

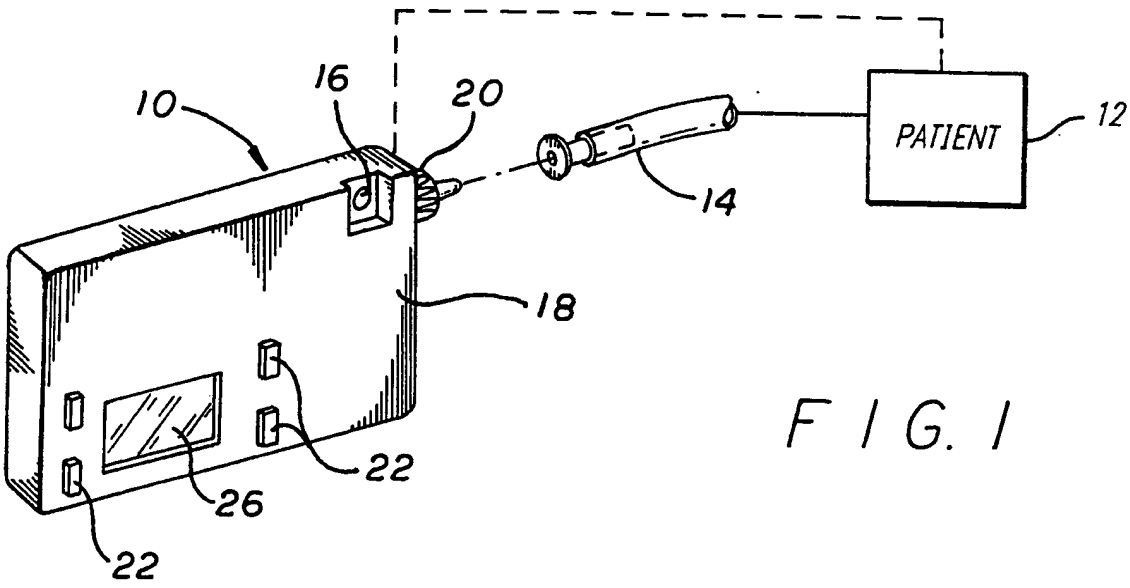


FIG. 1

FIG. 2

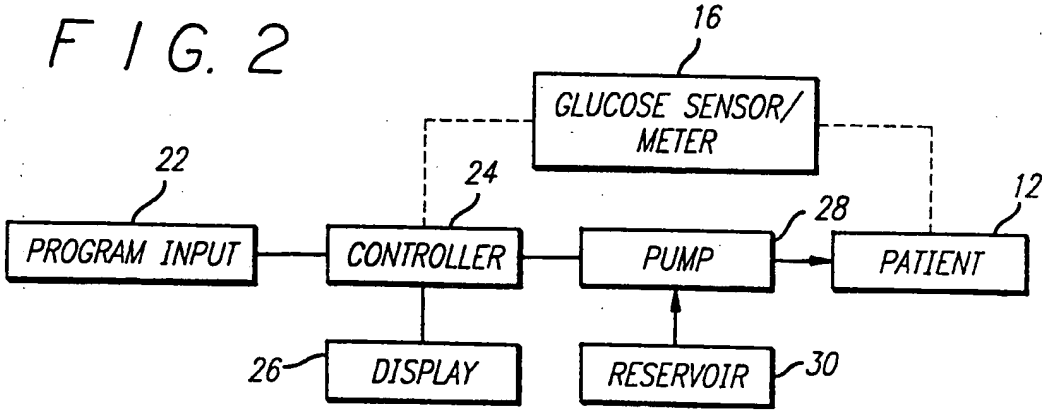


FIG. 3

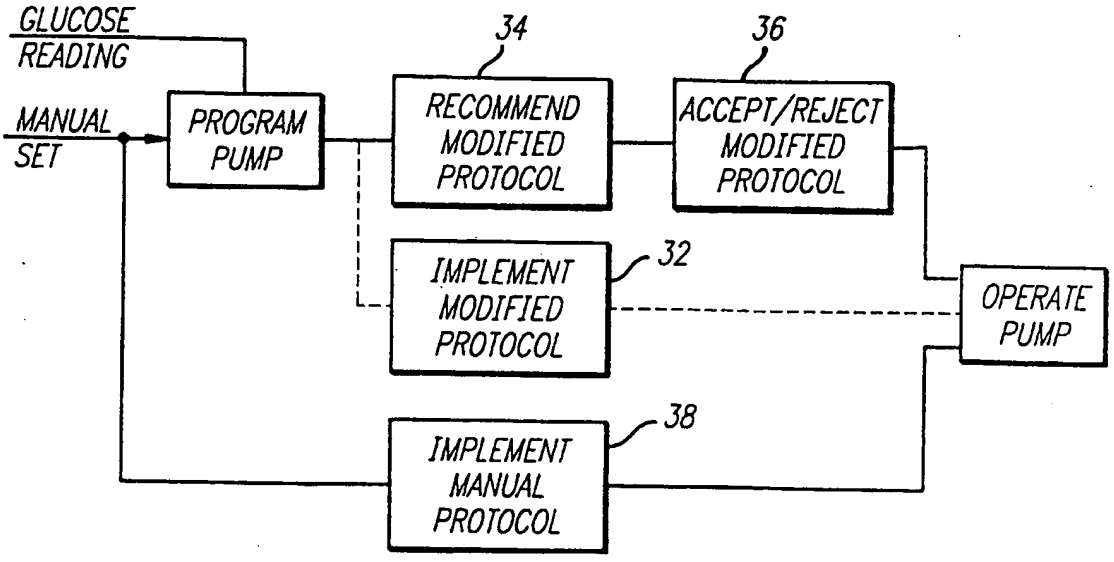


FIG. 4

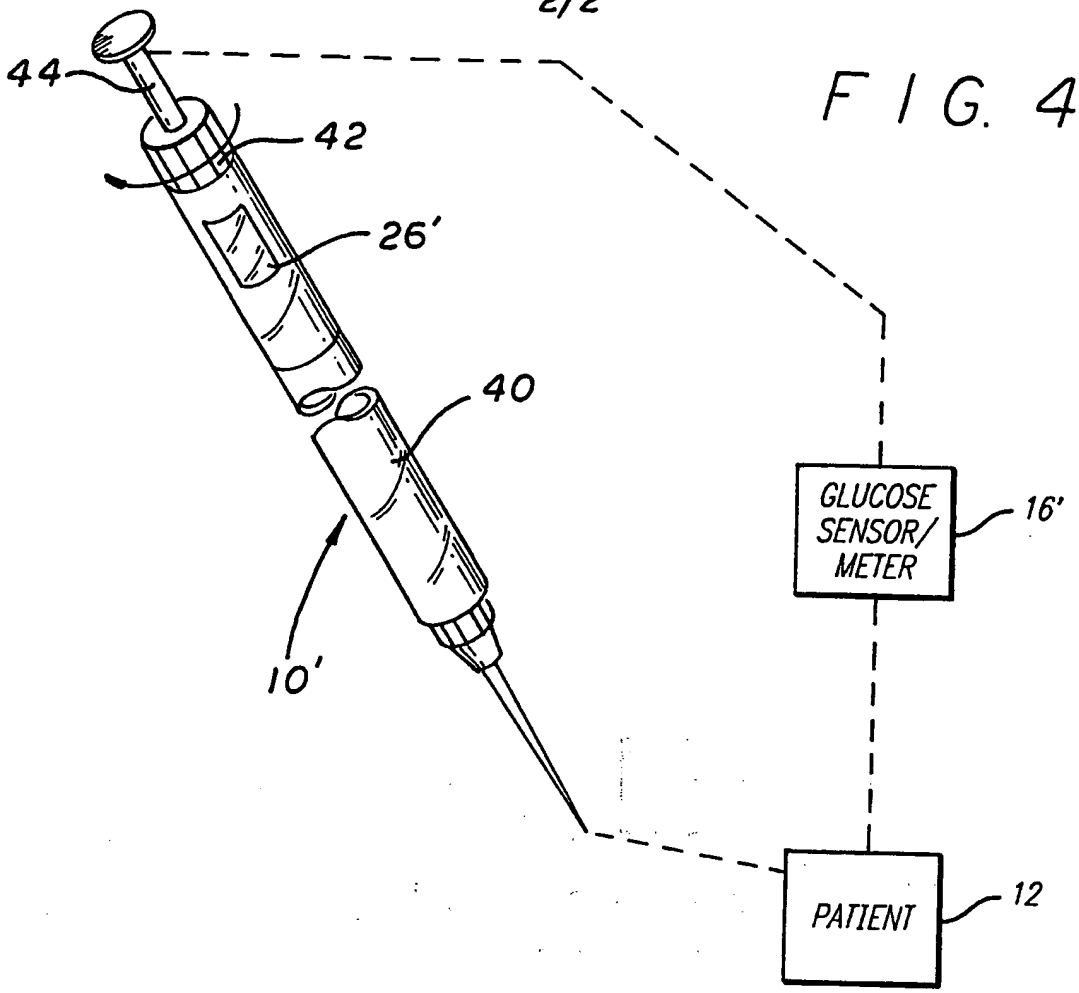
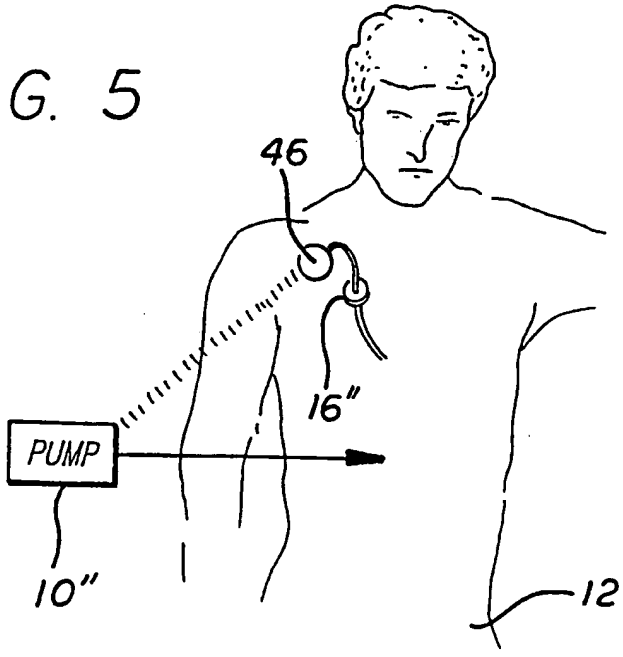

44
42
26'
40
10'
GLUCOSE SENSOR/ METER
16'
PATIENT
12

FIG. 5


46
16"
PUMP
10"
12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/06649

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/20
US CL :604/118

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/50-53, 65, 66, 93, 95, 118, 131, 132

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,871,351 (FEINGOLD) 03 October 1989, see entire reference.	1-3, 9, 10, 21-23 --- 4-8, 11-20
Y	US, A, 5,165,407 (WILSON ET AL.) 24 November 1992, see entire reference.	6, 18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search
18 JUNE 1996

Date of mailing of the international search report
09 JUL 1996

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Form PCT/ISA/210 (second sheet)(July 1992)★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/06649

B. FIELDS SEARCHED
Electronic data bases consulted (Name of data base and where practicable terms used):

APS

Search Terms: (Glucose, implant, sensor), (Infusion, glucose, current condition)